July 5, 2019

Urgent: Molded Products, Inc. Issues a Voluntary Recall on Medical Device

Dear ASD Healthcare Customer:

Molded Products, Inc. is initiating a voluntary medical device recall of the MPC Luer Lock Set. The affected lot information is listed below.

This product is being voluntarily recalled due to a complaint of mislabeling. Some unit of sale packages (bags of 100 sets) were found to be incorrectly labeled as Molded Products’ Male to Male Luer Adapters, Catalog # MPC-150. The case carton and individual polybags are correctly labeled as Molded Products’ MPC-125 Luer Lock Set, Lot # 20266. The issue could cause healthcare professionals to attempt to use the incorrect product for an unintended use. Molded Products, Inc. is requesting that the mislabeled product be immediately quarantined and returned for replacement.

Molded Products, Inc. provided the affected lot information below:

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Lot #</th>
<th>Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Luer Lock Set</td>
<td>20266</td>
<td>11/20/2022</td>
</tr>
</tbody>
</table>

To reduce any risk, we ask for your cooperation in taking the following action:

- Please examine your inventory immediately to determine if you have any impacted product in stock.
- If you do have inventory of the recalled lot number, please stop use of the product and quarantine impacted units.
- Contact Molded Products, Inc. directly at 800.435.8957 for next steps on returning impacted units for replacement.

For the full recall notice, please view the attached document on the following pages.

If you have any questions or concerns, please contact ASD Healthcare’s customer service at 800.746.6273.
June 13, 2019

Attn: Recall Coordinator
ASD Healthcare
345 International Blvd. #400A
Brooks, KY 40109

**URGENT MEDICAL DEVICE RECALL**
Molded Products, Inc. Luer Lock Set

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Catalog Number</th>
<th>Lot #</th>
<th>UDI</th>
<th>Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Luer Lock Set</td>
<td>MPC-125</td>
<td>20266</td>
<td>+B144MPC1251/$$52232420266N</td>
<td>11/20/2022</td>
</tr>
</tbody>
</table>

**For the Attention of:**
Materials Management/Recall Coordinator

**Description of the problem and health hazard(s):**
Molded Products, Inc. is voluntarily conducting a medical device recall of the MPC-125 Luer Lock Set based on a confirmed complaint of mislabeling. Some unit of sale packages (bags of 100 sets) were found to be incorrectly labeled as Molded Products' Male to Male Luer Adapters, Catalog # MPC-150. The case carton and individual polybags are correctly labeled as Molded Products' MPC-125 Luer Lock Set, Lot # 20266. The MPC-125 Luer Lock Set contains (2) non-injectable end caps used to cap female luer, whereas the MPC-150 Luer to Luer Adapter is used for blood circulation during hemodialysis procedures. Estimated % of lot affected: Less than 1%

**Unit of Sale Package (bag of 100 sets):**

![Correct Inner Polybag](image1)

![Incorrect Paper Directions for Use](image2)

Example of Mislabeling / Label Mix-up

This issue could cause healthcare professionals to attempt to use the incorrect product for an unintended use. Advisedlys, the MPC-125 Luer Lock Set will not connect in a recirculating path, it will only act as a non-injectable end cap.

Distribution of the affected lot occurred from February 15, 2019 thru May 30, 2019 and our records indicate you may have received the affected product.
Please take the following actions:

1. Please inspect your inventory to determine if you have any of the affected lot. Please inspect unit of sale packages to determine if the correct paper DFU (directions for use) is present, if the correct paper DFU is present the product is acceptable for use. If the incorrect paper DFU for the MPC-150 Male to Male Luer Adapter is present, please quarantine the mislabeled product and return to Molded Products, Inc. for replacement.
2. Share this recall notification will all users of the product to ensure they are also aware of this recall.
3. Contact Molded Products immediately at 800-437-8957 so that Molded Products may acknowledge your receipt of this notification and process your product replacement.

Actions taken by Molded Products, Inc.:

1. Corrective actions have been initiated to prevent recurrence of the identified root cause.
2. Molded Products, Inc. will provide replacement for all returned inventory.

Contact Information:
Please use the contacts provided below for complaints, adverse event reports, or questions regarding this recall.

<table>
<thead>
<tr>
<th>Molded Products, Inc. Contact</th>
<th>US Contact Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Customer/Technical Support</td>
<td>800-435-8957 Monday – Friday 8:00am-4:30pm (CT)</td>
</tr>
</tbody>
</table>

Molded Products is committed to maintaining a reputation of excellence and continually strives to provide high quality products to the healthcare industry. We apologize for any inconvenience this issue may have caused you and thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

Sincerely,

Sheri Tyrrel
Regulatory Affairs Manager

[Signature]

Rebecca Herning
President